

5.60.015

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2024
<b>Subsection:</b>	Central Nervous System Drugs	<b>Original Policy Date:</b>	April 14, 2017
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**Last Review Date:** March 8, 2024

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## Austedo

### Description

#### Austedo (deutetrabenazine)

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#### Background

Austedo (deutetrabenazine) is FDA approved for the treatment of chorea (involuntary jerky movements) associated with Huntington's disease (HD). Austedo is also indicated for the treatment of tardive dyskinesia (TD). HD is a progressive neurological disorder which may cause changes in mood, cognition, chorea, rigidity, and functional capacity over time. Although the exact mechanism is unknown, Austedo is believed to exert its effects through reversible depletion of monoamines from nerve terminals. Major circulating metabolites of Austedo ( $\alpha$ -dihydrodeutetrabenazine [HTBZ] and  $\beta$ -HTBZ) reversibly inhibit VMAT2, which decreases the uptake of monoamines into synaptic vesicles and depletes monoamine stores (such as dopamine, serotonin, norepinephrine, and histamine) (1).

#### Regulatory Status

FDA-approved indications: Austedo is a vesicular monoamine transporter 2 (VMAT2) inhibitor indicated for: (1)

- The treatment of chorea associated with Huntington's disease
- The treatment of tardive dyskinesia in adults

Austedo carries a boxed warning regarding the increased risk of depression and suicidal thoughts and behavior (suicidality) in patients with Huntington's disease. The risks of depression and suicidality should be balanced with the clinical need of Austedo therapy for the control of chorea. Austedo is contraindicated in patients who are actively suicidal, and in patients with untreated or inadequately treated depression (1).

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Prescribers should periodically re-evaluate the need for Austedo in their patients by assessing the effect on chorea and possible adverse effects, including sedation/somnolence, depression and suicidality, parkinsonism, akathisia, restlessness, and cognitive decline. It may be difficult to distinguish between adverse reactions and progression of the underlying disease; decreasing the dose or stopping the drug may help the clinician to distinguish between the two possibilities. In some patients, the underlying chorea itself may improve over time, decreasing the need for Austedo (1).

Austedo is contraindicated in patients with impaired hepatic function. Austedo is also contraindicated in patients taking MAOIs, reserpine or tetrabenazine. Austedo should not be used in combination with an MAOI, or within 14 days of discontinuing therapy with an MAOI. Reserpine binds irreversibly to VMAT2 and the duration of its effect is several days. Prescribers should wait for chorea to reemerge before administering Austedo to help reduce the risk of overdose and major depletion of serotonin and norepinephrine in the central nervous system. At least 20 days should elapse after stopping reserpine before starting Austedo. Austedo may be initiated the day following discontinuation of tetrabenazine (1).

Austedo should also be avoided in patients with congenital long QT syndrome and in patients with a history of cardiac arrhythmias. Also, concomitant use of strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine, quinidine, bupropion) has been shown to increase the systemic exposure to the active dihydro-metabolites of deutetabenazine by approximately 3-fold. The daily dose of Austedo should not exceed 36 mg per day in patients taking strong CYP2D6 inhibitors. Austedo should be avoided in patients with congenital long QT syndrome or with arrhythmias associated with a prolonged QT interval (1).

When clinically appropriate, pharmacologic interventions may be considered for patients who are developing signs of TD. The two main strategies are discontinuation of the offending drug and switching from first to second generation antipsychotic drugs. For patients with a diagnosis of TD, additional pharmacologic interventions include the following: use of benzodiazepines, botulinum toxin injections, tetrabenazine, or anticholinergic drugs to control symptoms of TD, or paradoxically, resuming treatment with antipsychotic drugs in order to suppress TD (2).

Two commonly used scales, the Abnormal Involuntary Movement Scale (AIMS) and Extrapyrimal Symptom Rating Scale (ESRS) are used to evaluate the severity of the tardive dyskinesia (3-4).

Safety and efficacy of Austedo have not been established in pediatric patients (1).

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## Related policies

Ingrezza, Xenazine

## Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Austedo may be considered **medically necessary** if the conditions indicated below are met.

Austedo may be considered **investigational** for all other indications.

## Prior-Approval Requirements

**Age** 18 years of age or older

### Diagnoses

Patient must have **ONE** of the following:

1. Moderate to severe tardive dyskinesia

**AND ALL** of the following:

- a. Inadequate treatment response, intolerance, or contraindication to **ONE** of the following:
  - i. Benzodiazepine
  - ii. Second generation antipsychotic (e.g., Seroquel, clozapine)
  - iii. Xenazine
- b. Documented baseline evaluation of the condition using **ONE** of the following scoring tools:
  - i. Abnormal Involuntary Movement Scale (AIMS)
  - ii. Extrapyramidal Symptom Rating Scale (ESRS)
- c. Prescriber has reduced the dosage or discontinued all causative medications including antipsychotic medication and metoclopramide (Reglan)
- d. Patient has a functional impairment that justifies treatment with Austedo

2. Chorea associated with Huntington's disease

**AND NONE** of the following for **ALL** indications:

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1. Actively suicidal
2. Untreated or inadequately treated depression
3. Concomitant use of a MAOI (monoamine oxidase inhibitor) (must be >14 days post discontinuing therapy)
4. Concomitant use of reserpine (must be >20 days post discontinuing therapy)
5. Hepatic impairment
6. Dual therapy with other vesicular monoamine transporter 2 (VMAT2) inhibitors

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## Prior – Approval *Renewal* Requirements

**Age:** 18 years of age or older

### Diagnoses

Patient must have **ONE** of the following:

1. Tardive dyskinesia

**AND** the following:

- a. Documented improvement using **ONE** of the following scores:
  - i. Abnormal Involuntary Movement Scale (AIMS)
  - ii. Extrapyrimalidal Symptom Rating Scale (ESRS)

2. Chorea associated with Huntington's disease

**AND NONE** of the following for **ALL** indications:

1. Actively suicidal
2. Untreated or inadequately treated depression
3. Concomitant use of a MAOI (monoamine oxidase inhibitor) (must be >14 days post discontinuing therapy)
4. Concomitant use of reserpine (must be >20 days post discontinuing therapy)
5. Hepatic impairment
6. Dual therapy with other vesicular monoamine transporter 2 (VMAT2) inhibitors

### [Policy Guidelines](#)

## Pre - PA Allowance

None

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## Prior - Approval Limits

**Quantity** 48 mg per day

**Duration** 12 months

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## Prior – Approval *Renewal* Limits

Same as above

## Rationale

### Summary

Austedo (deutetrabenazine) is approved for the treatment of chorea associated with Huntington’s disease (HD) or tardive dyskinesia (TD). Major circulating metabolites of Austedo ( $\alpha$ -dihydrotrabenazine [HTBZ] and  $\beta$ -HTBZ) reversibly inhibit VMAT2, which decreases the uptake of monoamines into synaptic vesicles and depletes monoamine stores. Austedo carries a boxed warning regarding the increased risk of depression and suicidal thoughts and behavior (suicidality) in patients. Austedo is contraindicated in patients with impaired hepatic function. Austedo is also contraindicated if used in combination with MAOIs, reserpine, or tetrabenazine. Safety and efficacy of Austedo have not been established in pediatric patients (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Austedo while maintaining optimal therapeutic outcomes.

### References

1. Austedo [package insert]. Parsippany, NJ: Teva Neuroscience, Inc; September 2023.
2. G Gharabawi, C Bossie, et al. Abnormal Involuntary Movement Scale (AIMS) and Extrapyramidal Symptom Rating Scale (ESRS): Cross-scale comparison in assessing tardive dyskinesia. *Schizophrenia Research* 77 (2005) 119–128.
3. G Chouinard, H Margoese. Manual for the Extrapyramidal Symptom Rating Scale (ESRS). *Schizophrenia Research* 76 (2005) 247–265.
4. UpToDate: Tardive dyskinesia: Prevention, prognosis and treatment. January 2021.

## Policy History

Date	Action
April 2017	Addition to PA

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June 2017	Annual editorial review Change of Severe hepatic impairment requirement to Hepatic impairment per SME
September 2017	Annual Review Addition of indication of tardive dyskinesia and no dual therapy with other vesicular monoamine transporter 2 (VMAT2) inhibitors and change in quantity limits of the 6mg from 720 to 450 tabs Addition of prescriber has reduced the dosage or cessation of all offending medications including antipsychotic medication and metoclopramide (Reglan); and patient has a functional impairment that justifies treatment with Austedo per SME
December 2017	Annual review
March 2019	Revised quantity limits to 4 per day of all strengths
June 2019	Annual review
May 2020	Removed specific AIMS and ESRS score requirements per FEP
June 2020	Annual review
March 2021	Annual editorial review and reference update
March 2022	Annual review and reference update
March 2023	Annual review and reference update. Changed policy number to 5.60.015
May 2023	Per PI update, changed quantity limit from 360 per 90 days to 48 mg per day
June 2023	Annual review
September 2023	Annual review
December 2023	Annual review and reference update
March 2024	Annual review

## Keywords

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**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.**